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# Mechanical versus pharmacomechanical thrombolysis for the treatment of thrombosed dialysis access grafts

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**Mechanical versus pharmacomechanical thrombolysis for the treatment of thrombosed dialysis access grafts.** Pharmacomechanical thrombolysis offers the first practical approach for non-surgical therapy of thrombosed dialysis access grafts. This technique involves both lysis using a fibrinolytic enzyme and mechanical maceration of the clot. The technique can be accomplished in a short period of time, has a high degree of success and has a low level of complications. To evaluate the effectiveness of the mechanical aspects of this technique used alone without the lytic enzyme, a study was designed in which 103 cases of thrombosed PTFE grafts were randomly assigned to either a mechanical (M) group consisting of 55 cases or a pharmacomechanical (PM) group consisting of 48 cases. Both groups were treated in an identical manner using crossed pulse-spray catheters, except that in the M group heparinized saline was used as the pulsing agent while in the PM group concentrated urokinase was used. The two groups were completely comparable in all other respects. The combined procedure of thrombolysis and angioplasty was successful in restoring flow in 92.8% of the M group and 93.8% of the PM group. Life table analysis revealed 74%, 65%, 58% and 37% function in the M group at 15, 30, 60 and 90 days, respectively. The rates for the PM group at the same time intervals were 77%, 72%, 62% and 46%. In none of these parameters was there any significant difference between the two groups. The mean time required for the procedure in the M group was shorter because of the time delay between pulses of enzyme in the PM group built into the technique which was used. Only local complications were seen in either group and consisted of small hematomas at previous needle puncture sites. There was no significant difference between the two groups in this regard. It is concluded that mechanical thrombolysis using saline pulses generated by crossed pulse-spray catheters followed by balloon maceration and dilation is a safe technique and is as effective as pharmacomechanical thrombolysis for the treatment of thrombosed dialysis access grafts.

A patent vascular access is critical to the treatment of the chronic hemodialysis patient. When patency is lost, restoration of function is urgent. An inability to perform dialysis in a timely manner is a critical problem that can result in patient morbidity and mortality. When presented with a patient having a thrombosed vascular access graft, most nephrologists have only two choices, either send the patient to surgery or insert a central venous dialysis access catheter. Either choice may be associated with problems. The first frequently results in an inordinate delay in dialysis and perhaps a period of hospitalization while exposing the patient to the risks of pain, blood loss and possible infection. The second is associated with the immediate and long-term risks of infection, less than optimum dialysis, and the possibility of central venous stenosis. The ideal solution would be the availability of a rapid, safe, effective and minimally invasive out-patient procedure for the restoration of graft function, a technique that could be applied by the nephrologist and allow the patient to be quickly returned to the dialysis unit for timely effective treatment. Thrombolysis has been studied for the past 20 years as a possible candidate for this role [1–13].

Until recently, a practical approach to thrombolysis in the dialysis patient has been an elusive goal. Various techniques have been attempted, but there have been major problems and the results have frequently been discouraging. Early attempts used protocols that required prolonged infusion of large doses of the lytic enzyme. Patients often required hospitalization for several days, bleeding complications were common, there was risk of allergic reactions to the enzyme, and the rate of success was disappointingly low [1–9].

Recently, a thrombolysis technique has been developed incorporating a combination of enzyme lysis with urokinase administered using pulse-spray catheters followed by mechanical maceration and removal of the clot. This approach, referred to as pharmacomechanical thrombolysis, is the first to prove practical for use in the dialysis patient. Using this combination of pharmacological and mechanical factors, over 98% of cases can be successfully treated within one to two hours with a very low incidence of side effects [10–13].

This study was undertaken in order to determine the effectiveness of the mechanical aspects of pharmacomechanical thrombolysis used alone in the treatment of thrombosed dialysis access grafts without the presence of the pharmacologically active lytic enzyme.

## Methods

### *Design of the study*

Only dialysis patients having thrombosed polytetrafluroethylene (PTFE) vascular access grafts were entered into the study. Either an infected graft or the presence of a contraindication to the use of fibrinolytic agents were disqualifications for the study. After giving informed consent, the patients were randomly assigned to either the pharmacomechanical (PM) or the mechanical (M) groups. A computer generated table of random numbers was used for this purpose. Patients with an odd number were assigned to the PM group and those with an even number were assigned to the M group. Each episode of thrombosis treated with thrombolysis in a patient having repeated episodes was treated as a separate case for the purposes of the study. Both groups were treated in a similar fashion except that in the M group heparinized saline was used as the pulsing agent to produce mechanical clot lysis and in the PM group concentrated urokinase was used. Both groups were

**Table 1.** Thrombolysis technique

| |
|---|
| Graft entered with needle in up-stream direction |
| Straight graft—adjacent to arterial anastamosis |
| Loop graft—low on venous side of loop |
| Guide wire (glide) passed up to level of superior vena cava |
| Pulse-spray catheter inserted and passed up to central vein |
| Used to inject medications and perform a venogram |
| If severe venous or anastamotic stenosis present |
| Pulse-spray catheter removed and replaced with angioplasty catheter |
| Stenosis dilated |
| Pulse-spray catheter replaced |
| Otherwise, continue |
| Insert occlusion wire into pulse-spray catheter and attach valve assembly |
| Graft entered with needle in down-stream direction |
| Adjacent to venous anastamosis—straight or loop graft |
| Guide wire (glide) passed through graft and across arterial anastamosis |
| Pulse-spray catheter inserted and passed to but not across arterial anastamosis |
| Insert occlusion wire into pulse-spray catheter and attach valve assembly |
| Pulse with agent (saline or urokinase) |
| Remove pulse-spray catheters |
| Use angioplasty balloon throughout entire graft |
| Macerate residual clot |
| Dilate areas of stenosis |
| Insert embolectomy balloon at venous anastamosis site—through a sheath |
| Down stream direction across arterial anastamosis |
| Pull back across anastamosis—gently |
| Pull back through entire graft—vigorously |
| Flush venous end of graft with saline |
| Angioplasty of any remaining venous stenosis lesion |
| Verify patency and internal appearance with venogram |
| Remove all objects from graft and obtain hemostasis (thrombin gelatin sponge) |

evaluated for effectiveness and safety of the procedure in the immediate and long-term time periods.

### *Thrombolysis technique*

The same basic technique was used in both groups for thrombolysis (Table 1) and was similar to that described by Bookstein and Valji [12], the major difference being the period of time between pulses of lytic enzyme (see below). First, a thin wall needle (Baxter Healthcare Corp., Round Lake, Illinois, USA) was inserted into the graft. In straight grafts the insertion point was approximately 4 cm above the arterial anastamosis in a downstream direction (toward the venous anastamosis). In loop grafts the needle was placed low on the venous side of the loop, just beyond the curve of the loop. A 150 cm straight guide wire (glide wire, Medi-Tech Inc.) was passed through the needle and, if possible, up to the level of the superior vena cava. Thrombolysis was not attempted unless a guide wire could be passed through the thrombosed graft and across any area of stenosis within the graft or the draining veins. This was necessary to assure that flow could be established once the clot was lysed. Cases in which a wire could not be passed were dropped from the study and were not used in any comparisons or calculations.

Once the guide wire was in place, the opening was dilated using a 5F dilator. A pulse-spray catheter (Angio Dynamics Inc.) with a 10 cm infusion length was then passed over the wire and advanced as far as the length of the catheter (40 cm) would permit or until the superior vena cava was reached. This was used as a straight catheter to inject medications and to perform a venogram. Each patient was given 5,000 U of heparin, 1 g of cephazolin (Squibb, Princeton, New Jersey, USA) and midazolam hydrochloride (Versed, Hoffman-LaRoche, Research Triangle Park, North Carolina, USA) for sedation. The venogram was performed to identify areas of stenosis and to determine the extent of the thrombosis as the catheter was slowly withdrawn back into the graft. If venous stenosis was found, the pulse-spray catheter was removed and replaced with an angioplasty catheter. The lesion was dilated using a standard technique [12] and the pulse-spray catheter was replaced.

This venous pulse-spray catheter was positioned so that the tip of the catheter was at the venous anastamosis. The thin wall needle was then inserted approximately 4 cm from the venous anastamosis in both straight and loop grafts pointing in an upstream direction (toward the arterial anastamosis). The guide wire was passed up to and across the arterial anastamosis. After using a 5F dilator to dilate the opening, the second pulse-spray catheter was inserted and positioned so that the tip was at the arterial anastamosis. The infusion length of this arterial pulse-spray catheter used in straight grafts was 10 cm; a 20 cm length was used in loop grafts. Both catheters were 40 cm in overall length and had a 1.5 cc fill volume. With the two catheters placed in this crossed fashion the entire length of the graft could be covered.

These catheters are supplied with an occlusion wire to occlude the distal tip of the catheter and a dual check valve with Y-connector to facilitate the administration of the lytic agent. These were attached and the two systems were connected using a special bifurcated line (Angio Dynamics) to permit simultaneous injection into both catheters. A 1 ml syringe was used to administer the lytic agent. In the PM group 250,000 IU of urokinase (Abbott) in 10 ml containing 4,000 U of heparin was used as the lytic agent. The total fill-volume of the catheters is 3 cc (1.5 cc each), this amount of urokinase was injected to prime the catheters and then they were pulsed. Repeated pulses of approximately 0.6 ml (delivering 0.3 ml to each catheter) were forcibly administered at four minute intervals until flow could be detected within the graft. The return of flow was determined by frequent palpation of the graft to detect the presence and distribution of the pulse, or occasionally by Doppler. When flow was present throughout the graft, the catheters were removed and the next step of the procedure was initiated.

In the M group 10 ml of saline containing 2,000 U of heparin was used for lysis. This was pulsed into the catheters in 0.6 ml volumes in the same manner using rapid, very forceful pulses. Following this process, the pulse-spray catheters were removed and the procedure was continued. At this point flow was generally present, but was not considered essential. Complete thrombolysis was not a goal in either group at this point. In the PM group, the return of flow was the end point for pulsing. In the M group there was no prerequisite for proceeding with the procedure, it was automatic.

After removing the pulse-spray catheters, the angioplasty balloon catheter was inserted and the entire length of the graft was dilated to macerate residual clot and dilate any stenosis that was present within the graft. A 5F sheath was inserted at the

former site of the arterial pulse-spray catheter. Through this sheath a 4F arterial embolectomy catheter (Fogarty, Baxter Healthcare Inc.) 40 cm in length was inserted. This was passed across the arterial anastamosis, inflated using a 1 ml contrast-filled syringe and pulled back through the entire length of the graft up to the point of insertion of the sheath. Only gentle pressure was used until the arterial anastamosis was crossed, then firm pressure was applied within the graft. If flow through the graft did not appear to be optimum at this point, the procedure with the embolectomy balloon was repeated several times. If flow was still poor, the arterial anastamosis was visualized angiographically. In the cases with stenosis of the arterial anastamosis, a 4 mm angioplasty balloon catheter was placed across the anastamosis using a guide wire. The stenosis was dilated, then the embolectomy catheter was used again. At the end of the procedure, the venous end of the graft was flushed with saline.

An angiogram was performed at this point to verify that the graft was clear of thrombus and that any stenotic lesions previously present had been dilated. If the angiographic appearance was satisfactory, all objects were removed from the graft and digital pressure was applied to the two graft puncture sites using thrombin (Thrombostat, Park-Davis, Morris Plains, New Jersey, USA) soaked gelatin sponge (Gelfoam, Upjohn Co., Kalamazoo, Michigan, USA). Hemostasis generally required two to five minutes.

A record was maintained of the time required to perform each combined procedure (angiogram, thrombolysis and angioplasty). This time did not include the time required to prepare and drape the patient's arm, and it did not include the time required for hemostasis at the end of the procedure. In all instances the procedures were performed in the angiography suite on an outpatient basis. Following the procedure most patients were sent directly to dialysis.

### *Patient evaluation*

Each case was evaluated for complications of the lytic enzyme, evidence of distal embolization beyond the arterial anastamosis, and clinical evidence of pulmonary embolization. This evaluation was performed immediately and was continued in the dialysis unit as the patients were followed on dialysis subsequent to the treatment. Chest x-rays were not routinely done. In addition, each case had long-term follow-up to determine the duration of patency of the graft following the combined procedure. The history of each patient's access graft was reviewed to determine its age, if any procedure had been previously performed on the graft and the duration of patency of such previous therapy.

### *Criteria for success*

A distinction was made between success of the combined procedure, thrombolysis and angioplasty, and the thrombolysis procedure alone. The combined procedure was considered successful if the thrombus could be lysed and unobstructed flow through the graft and draining veins could be established sufficiently and persistently enough to allow for one subsequent normal dialysis. Thrombolysis was counted as successful if the thrombus could be lysed and eliminated as determined angiographically. The period of time which elapsed until the graft thrombosed again or required another invasive procedure such as surgical revision or angioplasty was counted as the duration of patency of the combined procedure.

### *Statistical analysis*

The Kaplan-Meier method was used to calculate the life table analysis data. Comparisons of long-term patency for the different groups were made using the generalized Wilcoxon test for comparing data derived from life table analysis involving censored observations. To compare the differences in time required to perform the combined procedure in the two groups, the Wilcoxon rank sum test was applied. The Spearman rank correlation test was used to compare the differences in duration of patency between paired groups. The chi-square test was utilized to determine the statistical significance of differences in the incidence of several different variables noted between the two groups. Correlation coefficients were calculated using the least squares method. In all instances a probability value of 0.05 or less was used to determine statistical significance.

## Results

A total of 104 cases of thrombosed vascular access grafts in 78 patients were entered into the study over a period of seven months. Several patients had more than one episode (maximum of 4). Random distribution of the cases resulted in 49 cases in the PM group and 55 cases in the M group. In only one case was the procedure not initiated because of an inability to pass the guide wire across an area of venous occlusion above the graft. This case had been randomized to the PM group, but was dropped from the study leaving 48 cases in this group. In the remaining 103 cases the procedure appropriate for the group was performed. Since the thrombotic event for each patient generally occurred at some time between regularly scheduled treatments and was not recognized until the patient presented for dialysis, the age of the thrombosis at the time of the procedure was not precisely known. For most patients it was less than 44 hours old where the interdialytic interval was 48 hours, and less than 68 hours old when the interval was 72 hours. In one case in the PM group the graft had been thrombosed for four days and in one patient in the M group the graft had been occluded for 13 days. Except for these two cases the thrombolytic procedure was performed on the same day that the thrombosed graft was identified, generally within a matter of one to two hours. In many cases it was possible to have the patient back on dialysis within two to three hours of the diagnosis of a clotted graft. Within the M group, 27 cases had straight grafts and 28 had loops. Three of the loops were in the upper arm and one was in the thigh. Within the PM group, 20 cases had straight grafts and 28 had loops (Table 2). Of the loops, three were in the upper arm. These differences were not significant ($P = 0.543$).

Although thrombolysis successfully removed the thrombus in 100% of the cases in both groups (Table 3), the overall success rate for the combined procedure was 92.8% in the M group and 93.8% in the PM group. The difference in these two numbers was because flow could not be restored in four cases (7.2%) of the M group and three cases (6.2%) of the PM group. The problem in each of these instances was the presence of a stenotic lesion that could not be repaired by angioplasty. This difference was not statistically significant ($P = 0.832$).

Venous stenotic lesions (Table 1) were present in 45 (93.8%)

**Table 2.** Characteristics of groups

| Category | Group | |
|---|---|---|
| | Mechanical | Pharmacomechanical |
| Number | 55 | 48 |
| Agent | Saline | Urokinase |
| Venous stenosis[a] | 93.8% | 94.5% |
| Arterial stenosis[a] | 9.1% | 10.4% |
| Graft age *months*[a] | | |
| median | 10.6 | 11.8 |
| range | 0.5 to 114.7 | 0.5 to 138 |
| Graft type | | |
| straight | 27 | 20 |
| loop | 28 | 28 |

[a] Differences between groups were not statistically significant ($P$ = 0.532, 0.816, 1.00) for venous stenosis calculations were based upon frequency and location of specific category of lesion

**Table 3.** Immediate results of therapy

| Category | Group | |
|---|---|---|
| | Mechanical | Pharmacomechanical |
| Thrombolysis[a] | 100% | 100% |
| Function[a,b] | 92.8% | 93.8% |
| Time required[c] *min* | 48 | 58 |
| Complications[b] | | |
| local | 18% | 10.4% |
| distal[d] | 0% | 0% |
| systemic | 0% | 0% |

[a] The values listed refer to % success
[b] No statistically significant difference was noted ($P$ = 0.832, 0.264)
[c] The differences noted were statistically significant ($P$ = 0.008)
[d] Refers to arterial embolization beyond the arterial anastamosis

of the PM cases and 53 (94.5%) of the cases of the M group. The distribution of venous lesions for the M group was as follows: within the graft 32.7%, venous anastamosis 69%, peripheral venous 45.4%, central venous 5.4%. In 47.3% of these cases lesions were present at more than one site. In the PM group the distribution was: within the graft 39.6%, venous anastamosis 53.3%, peripheral venous 46.7%, central venous 4.6%. Lesions were present in more than one of these locations in 22.9%. Stenosis at the arterial anastamosis was present in five members of each group. This represented 9.7% of the total patients treated. None of these differences were significant ($P$ = 0.532, 0.816).

The mean time required to perform the combined procedure in the M group was 48 minutes (median 45) with a range of 24 to 88 minutes. In the PM group, the mean time required was 58 minutes (median 55) with a range of 30 to 135 minutes (Table 3). The difference between the time required for the two groups was statistically significant ($P$ = 0.008). This difference in time was due to the time delay between pulses in the PM group. The mean dosage of urokinase used in the PM group was 140,000 IU (median 135,000 IU) with a range of 100,000 to 250,000 IU. The 3 cc of urokinase used for the fill volume of the catheters was included in this total.

No instance of peripheral embolization was observed and no patient had any clinical suggestion of pulmonary embolization. Local complications in the form of a small hematoma 2 cm by 4 cm or less in size were seen in 10 cases of the M group and five cases of the PM group (Table 2). These were all at fresh needle puncture sites that had been created at the dialysis unit prior to recognition that the graft was thrombosed. They did not result in significant problems. The difference between the incidence of these complications in the two groups was not statistically significant ($P$ = 0.264).

**Table 4.** Long-term results of therapy[a]

| Days post-therapy | Group[b] | |
|---|---|---|
| | Mechanical | Pharmacomechanical |
| 15 | 74% | 77% |
| 30 | 65% | 72% |
| 60 | 58% | 62% |
| 90 | 37% | 46% |

[a] Refers to duration of patency following the combined procedure (life table analysis)
[b] The differences noted between the groups were not significant ($P$ = 0.17)

The age of the access grafts (Table 1) in the M group had a mean of 22.6 months (median 10.6 months) with a range of 0.5 to 114.7 months. In the PM group the graft age had a mean of 21.4 months (median 11.8 months) with a range of 0.5 to 138 months. There was no significant difference between the two groups ($P$ = 1.00). In addition to the fact that the access had been in place for only 15 days in one patient of each group, several patients of each group had had an invasive procedure less than 30 days prior to the study thrombolysis. In the M group 10 patients had a surgical thrombectomy three to 11 days, two had a surgical revision of their graft two and 14 days, and two had a thrombolysis two and three days prior to the study thrombolysis. In the PM group seven patients had a surgical thrombectomy five to 25 days, two had a surgical revision at six and 10 days, and six had prior thrombolysis from two to 28 days prior to the their study thrombolysis. None of these was associated with any adversity when the study thrombolysis was performed.

The duration of patency (Table 4) for the combined procedure in the M group was as follows: 15 days 74%, 30 days 65%, at 60 days 58% and at 90 days 37%. For the PM group the duration of patency was: 15 days 77%, 30 days 72%; 60 days 62%; and at 90 days 46%. These values were determined by life table analysis. A comparison of the data for the two groups revealed no significant difference at any period ($P$ = 0.17).

Most of these cases had had previous procedures performed upon their grafts. The duration of patency for this previous therapy was determined and compared to the duration of patency observed in these cases following the combined procedure. A general correlation was seen between the two variables with a correlation coefficient of 0.312. Thirty-two of the cases in the M group had had a surgical thrombectomy as the procedure that immediately preceded the thrombotic event that was treated by thrombolysis. A comparison of the duration of patency for these two procedures (one surgical, the other non-surgical) in the same patient revealed that there was no statistically significant difference ($P$ = 0.30). The same comparisons in the PM group also showed no significant difference ($P$ = 0.30).

## Discussion

The availability to the nephrologist of a non-surgical technique to restore function to a thrombosed dialysis graft is an attractive goal in view of the frequency of this problem, the cost and frequent requirement for hospitalization, and the delay often associated with surgical therapy. The ability to quickly restore graft function in an outpatient setting in a safe, minimally invasive manner which permits timely dialysis without the need for central venous catheters would decrease costs, benefit patient morale and decrease morbidity. With recent improvements in the technique, thrombolysis could be a candidate for this position.

In the past 20 years, thrombolysis has undergone a significant evolution [1–13]. The history of this procedure as applied to the dialysis access started with techniques that were strictly pharmacological, involving infusion of high doses of lytic enzymes over periods of time ranging from two [6] to 72 [3] hours. Hospitalization was required, often within the intensive care unit. Success rates as low as 14% [5] were reported with bleeding complications as high as 57% [6], arterial embolization as high as 6% [8], allergic complications as high as 40% [3] and total complications as high as 85.7% [5]. As late as 1989, a study involving 67 cases was reported [9] in which the mean dose of urokinase used was 1,130,000 IU over a mean time of 15.2 hours with an immediate failure rate of 42%. In 18% of the cases the failure was due to bleeding that necessitated discontinuing the procedure, eight cases required blood transfusions. From the nephrologist's viewpoint this situation was impractical and unacceptable.

Recently, the major obstacles to effective and practical percutaneous therapy of thrombosed dialysis access grafts have been largely eliminated by the development of techniques to accelerate thrombolysis using a combination of fibrinolytic therapy with concentrated urokinase and mechanical clot maceration and removal [10–13]. This technique, referred to as pharmacomechanical thrombolysis (PMT), has yielded success rates greater than 95% using much smaller doses of enzyme with lysis times of 40 minutes or less with very few complications. Patients have been treated on an outpatient basis and have been returned to dialysis within 30 minutes of completing the procedure. The manner in which the treatment is accomplished allows for a combined procedure that involves angiography and angioplasty to evaluate the graft's status and correct not only the symptom (occlusion of the graft), but also the disease (venous stenosis).

In evaluating this procedure in our unit, it was noted that in several cases flow appeared within the graft very early, before a significant amount of lytic enzyme had been administered. In several cases flow was restored by simply inserting the catheters. This study was initiated to expand further on this observation and determine the effectiveness of using only the mechanical aspects of PMT to restore function to thrombosed grafts without the benefits of the lytic agent.

Over a period of seven months 103 patients with thrombosed PTFE grafts were studied in a controlled fashion with the cases being randomly assigned to a mechanical (M) group and a pharmacomechanical (PM) group. These groups were comparable in every respect (Table 2). The M group received only heparinized saline using crossed pulse-spray catheters while the PM group received the conventional concentrated urokinase, but with a slightly longer interval between pulses of enzyme than use by others, four versus 0.5 minutes [10–13]. Both groups were treated in an identical fashion except for the agent pulsed through the catheters.

The immediate response to therapy in the two groups was identical with 100% removal of the thrombus as defined by angiography. The restoration of function, which is a measure of the effectiveness of the combined procedure of thrombolysis and angioplasty was 92.8% for the M group and 93.8% for the PM group (Table 3). The difference between the rate of clot removal and restoration of flow was due to the presence of stenotic lesions that could not be treated with angioplasty. These rates represent the actual success of the techniques used, but the failures were not due to an inability to rid the graft of thrombus. These number were very similar to the data reported by Roberts et al [13], and is almost identical to that group's earlier data reported by Valji et al [11]. We noted that a slightly longer period was required for the PM group because of the waiting time of four minutes between pulses of the enzyme. Complications were all minor and caused no difficulty. No arterial emboli or clinical evidence of pulmonary emboli were noted in either group (Table 3). The long-term results (primary patency) which are largely a reflection of the success of the angioplasty procedure, were equivalent in the two groups (Table 4) and were very similar to those reported by Valji et al [11] in their series of PMT.

With mechanical thrombolysis small thrombi are undoubtedly being released into the circulation. The possibility of creating a dangerous pulmonary embolus has been a concern, but has not been seen. Mechanical removal of an occluding thrombus is not a totally new concept. Hunter et al [15] reported removing small thrombi using an angioplasty balloon and Trerotola et al [16] have used this as the primary treatment for thrombosed grafts. No clinical evidence of pulmonary emboli was noted by these investigators. Even with pharmacological [2–9] and pharmacomechanical [10–14] techniques, as flow returns, it is probable that small pieces of residual clot are being detached and carried centrally. This is especially likely to occur during the mechanical phase of PMT, since its advocates do not hesitate to begin the use of the angioplasty balloon within the graft despite the continued presence of residual mural thrombi [9–11]. Additionally, a platelet rich thrombus (white thrombus) is frequently present just upstream from the arterial anastamosis [11, 13, 17]. Roberts et al [13] reported the presence of this thrombus in 84 of 200 cases. This thrombus is resistant to fibrinolysis necessitating its mechanical removal with a balloon catheter as part of the PMT technique. In spite of the possibilities for pulmonary emboli, review of a cumulative total of over 650 cases of thrombolysis reported in the literature [2–13] reveals only one case of clinically evident pulmonary embolus [7], the symptoms of which were gone within 24 hours, and two cases of transient chest pain of undetermined etiology [11]. No clinical evidence to suggest pulmonary embolism was seen in any of the cases in this report. Even in those cases with repeated thrombolysis, no adverse sequelae were noted.

There are several observations that have been made by other investigators that were confirmed and extended in this report. The age of the graft [9] does not have any effect on the success

of thrombolytic therapy. The incidence of venous stenosis [9, 11] is greater than 90%, a figure significantly higher than that in surgical reports where angiography was not used. The duration of patency for the procedure that preceded the thrombolysis [9] correlated with the long-term patency of the graft following thrombolysis. A correlation coefficient of 0.312 was seen when the two were compared. In those cases in which a surgical thrombectomy had been done previous to the event treated by thrombolysis, no significant difference in duration of patency was seen for the two procedures in the same patients. This suggests that factors intrinsic to the patient and independent of the type of therapy may be important in determining duration of patency. Controlled studies are needed to further illuminate this issue.

The difficulty of prolonged bleeding from needle puncture sites reported by others was solved in this study by using a thrombin soaked gelatin sponge. Hemostasis was obtained in two to five minutes. The explanation for the need for significantly less urokinase in this study than has been reported by others [11–13] is not apparent. The possibility that the longer interval between pulses of lytic agent giving more time for enzymatic activity to take place must be considered as a possibility. Also, the criteria that have been used to determine when to terminate urokinase pulsing and proceed with the remainder of the procedure have not been made clear in these previous reports. In this study, when flow appeared, urokinase pulsing was discontinued. It seemed apparent that any further agent administered would be washed away by the flow and not be present at the site necessary for lytic action to take place.

In conclusion, mechanical thrombolysis using a macerating pulse of heparinized saline generated by crossed pulse-spray catheters followed by balloon maceration and dilation is as effective and safe to use for the treatment of thrombosed dialysis access grafts as pharmacomechanical thrombolysis. It has the advantage over pharmacomechanical thrombolysis of avoiding the cost of the lytic agent.

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